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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,965	04/11/2005	Matthew Gonda	2006636-0039	9899
24280 7590 02/20/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER				
PAK, MICHAEL D				
ART UNIT		PAPER NUMBER		
1646				
NOTIFICATION DATE		DELIVERY MODE		
02/20/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdoCKET@choate.com

### Office Action Summary

**Application No.**

10/508,965

**Applicant(s)**

GONDA ET AL.

**Examiner**

Michael Pak

**Art Unit**

1646

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,6-11,25,27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-11,25,27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Amendment filed October 14, 2008 has been entered.
2. Applicant's arguments filed October 14, 2009, have been fully considered but they are not found persuasive.
3. Claims 2-3, 5, 12-24, 26 and 28 are cancelled. Claims 1, 4, 6-11, 25, 27 and 29-33 are examined below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4, 6-11, 25, 27 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite or encompass the term "human Nav1.9 sodium channel protein or fragment thereof" which is confusing and ambiguous because it is not clear what is the metes and bounds of the term. The term "human" does not provide structural limitation to the sodium channel claimed and is not clear when a sodium channel is human. Applicant argue in their arguments regarding rejections under 35 USC 102 that Dibb-Haj

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et al. reference does not teach the human sodium channel yet the sequence structure appears to be same structurally. Furthermore, it is not clear when a sodium channel is human structurally since mutations can be created in the sodium channel which may be similar to both human and other species or none of the known structures and it is not clear where is the metes and bounds of the structure that is human versus some other sodium channel.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-2, 4, 6-11, 25, 27 and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dib-Hajj et al. (WO 2001/05831).

The reason for the rejection has been set forth in the previous office action.

The claimed expression vector comprising nucleic acid comprising SEQ ID NO:5 encodes SEQ ID NO:42 which is 100% identical to Dib-Hajj et al. nucleic acid encoding SEQ ID NO:4 of sodium channel (pages 9 and 16-18).

Applicants argue that Dib-Hajj et al. only disclose a partial sequence for human Nav1.9 (figure 8) and provide no teaching or suggestion that such partial sequence can be expressed in cells nor encode a sodium channel that produces a sodium current. However, the SEQ ID NO:42 is available in full sequence which is identical to SEQ ID NO:4 claimed. Applicant argue that Dib-Hajj et al. reference does not teach the human sodium channel yet the sequence structure appears to be same structurally. The sodium channel inherently produces the sodium current.

6. Claims 1-2, 4, 6-11, 25-27 and 29-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Dib-Hajj et al. (US 6,573,067).

The reason for the rejection has been set forth in the previous office action.

The claimed expression vector comprising nucleic acid comprising SEQ ID NO:5 encodes SEQ ID NO:42 which is 100% identical to Dib-Hajj et al. nucleic acid encoding SEQ ID NO:4 of sodium channel (columns 10, 17, 21 and 27).

Applicants argue that Dib-Hajj et al. only disclose a partial sequence for human Nav1.9 (figure 8) and provide no teaching or suggestion that such partial sequence can

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be expressed in cells nor encode a sodium channel that produces a sodium current. However, the SEQ ID NO:42 is available in full sequence which is identical to SEQ ID NO:4 claimed. Applicant argue that Dibb-Haj et al. reference does not teach the human sodium channel yet the sequence structure appears to be same structurally. The sodium channel inherently produces the sodium current.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Pak/  
Primary Examiner, Art Unit 1646  
13 February 2009